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Date: 12/31/02

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To: Examiner: G. Kishore Telephone Number: 308-2440

Group Art Unit: 1615

Facsimile No.: 703-305-3592

From: Thomas M. Cunningham Registration No.: 45,394

Telephone Number: 703-413-6563

Date: December 31, 2002

RE: U.S. Application Serial Number: 09/777,874

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COMMENTS

Communication

In the event that any fees are due, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge the required fees to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 CFR 1.136 for the necessary extension of time.

DOCKET NO.: 200427US0 CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Claudio CAVAZZA

: EXAMINER: G. KISHORE

SERIAL NO: 09/777,874 :

FILED: FEBRUARY 7, 2001

: GROUP ART UNIT: 1615

FOR: PHARMACEUTICAL COMPOSITION COMPRISING CARNITINE OR
ALKANOYL L-CARNITINE FOR THE PREVENTION AND
TREATMENT OF DISEASES BROUGHT ABOUT BY LIPID
METABOLISM DISORDERS

COMMUNICATION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Appellants note that the Petition under 37 C.F.R. 1.181, filed October 8, 2002, has been denied, because the Office believes the issue of whether or not the T-test is a conventional test of statistical significance is indicative of a difference of opinion between the Appellants and the Examiner, which is properly appealed to the Board.

The Appellants respectfully request that this application now be forwarded to the Board *inter alia* for a decision on this technical issue. Appellants respectfully request that the Board find as a matter of fact that T test significance scores are conventionally used to determine the statistical significance of differences between compared groups. The Board's attention is directed to the background materials on the T-test appended to both the Petition under 37 C.F.R. 1.181 and the Response filed June 6, 2002. Such a finding of fact--that T-test scores are conventional indicators of the significance of differences between groups--may be based on the Board's technical expertise or on other technical materials (such as the previously submitted background information on the T-test). In re Zurko, 46 USPQ2d 1691 (Fed. Cir.

1998), *rev'd sub nom. Dickenson v Zurko*, 50 USPQ2d 1930 (1999); 37 C.F.R. 1.196(b).

Secondly, while proposed (unentered) Claim 11 is not on appeal, the Appellants would like to clarify the record by pointing out that the response to the Petition under 37 C.F.R. 1.181 mischaracterizes the scope of Claim 20 as falling outside the limitations of Claim 11 (unentered). In fact, the subject matter of Claim 20 would fall within the scope of proposed Claim 11, because the composition of Claim 20, "wherein the weight ratio of the second component to the first component is: 1:1 to 1:100", would fall within the scope of proposed Claim 11's wherein clause, which requires that "said composition comprises at least 2 gr of component (i) per 100 gr and 1 gr of component (ii) per 100 grams". For instance, when Claim 20's ratio is 1:1, then Claim 11 could comprise 2 gr of component (i) and 2 gr of component (ii). When Claim 20's ratio is 1:100, then the composition of Claim 11 could comprise 2 gr of component (i) and 200 gr of component (ii). Thus, Claim 20 would further limit the ratios of ingredients specified by proposed Claim 11.

Appellants respectfully request that this application be forward in due course to the Board of Appeals and that the Board of Appeals reverse the Examiner's rejections.

Respectfully submitted,

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